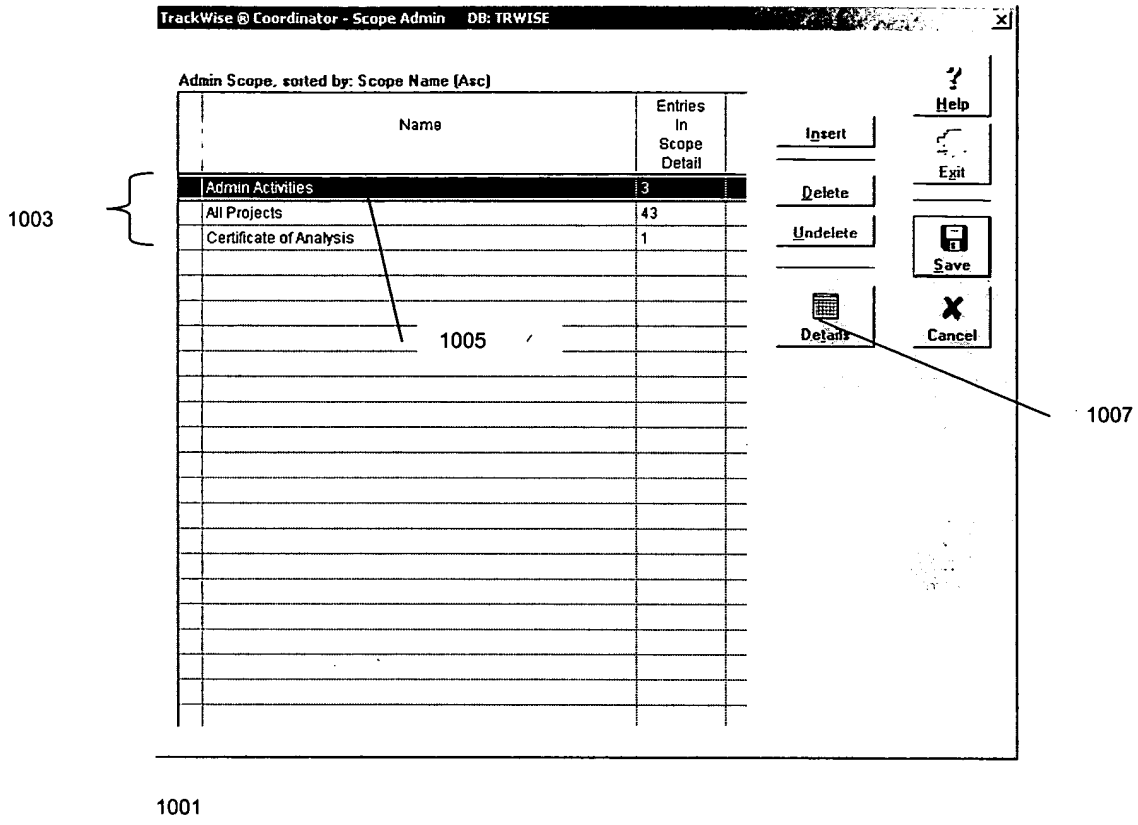

TrackWise ® Coordinator - Scope Admin DB: TRWISE
Admin Scope, sorted by: Scope Name (Asc)
Name
Entries In Scope Detail
Admin Activities 3
All Projects 43
Certificate of Analysis 1
Insert
Delete
Undelete
Details
Help
Exit
Save
Cancel
1003
1005
1007
1001

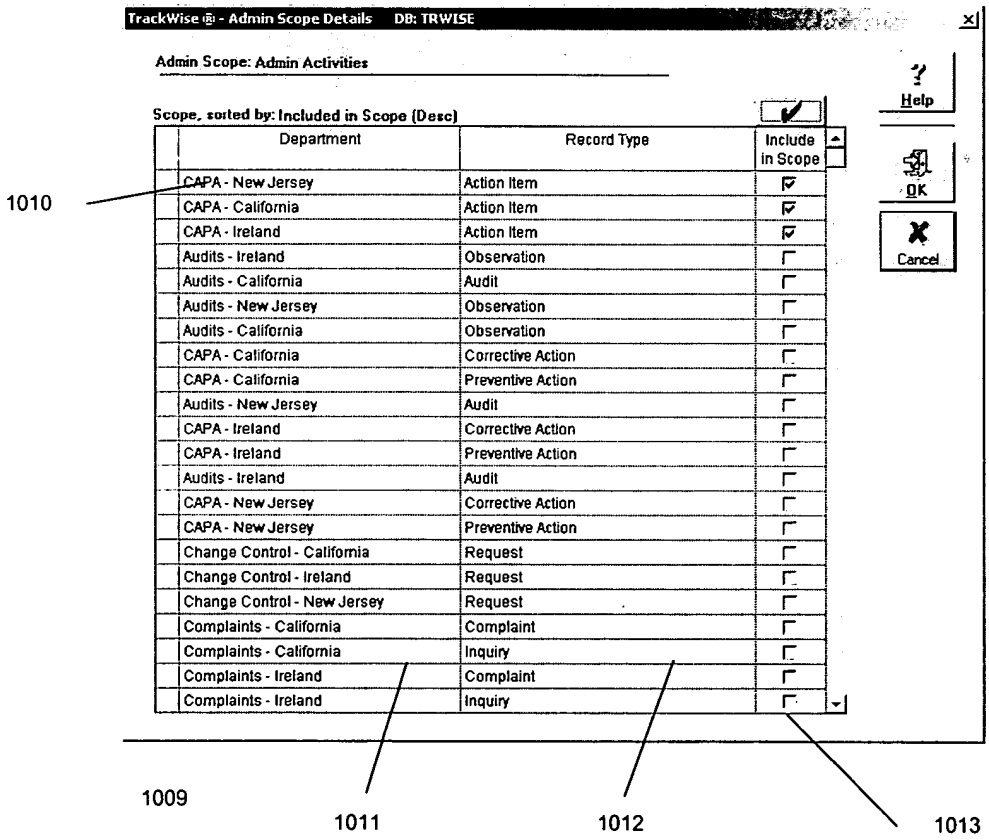
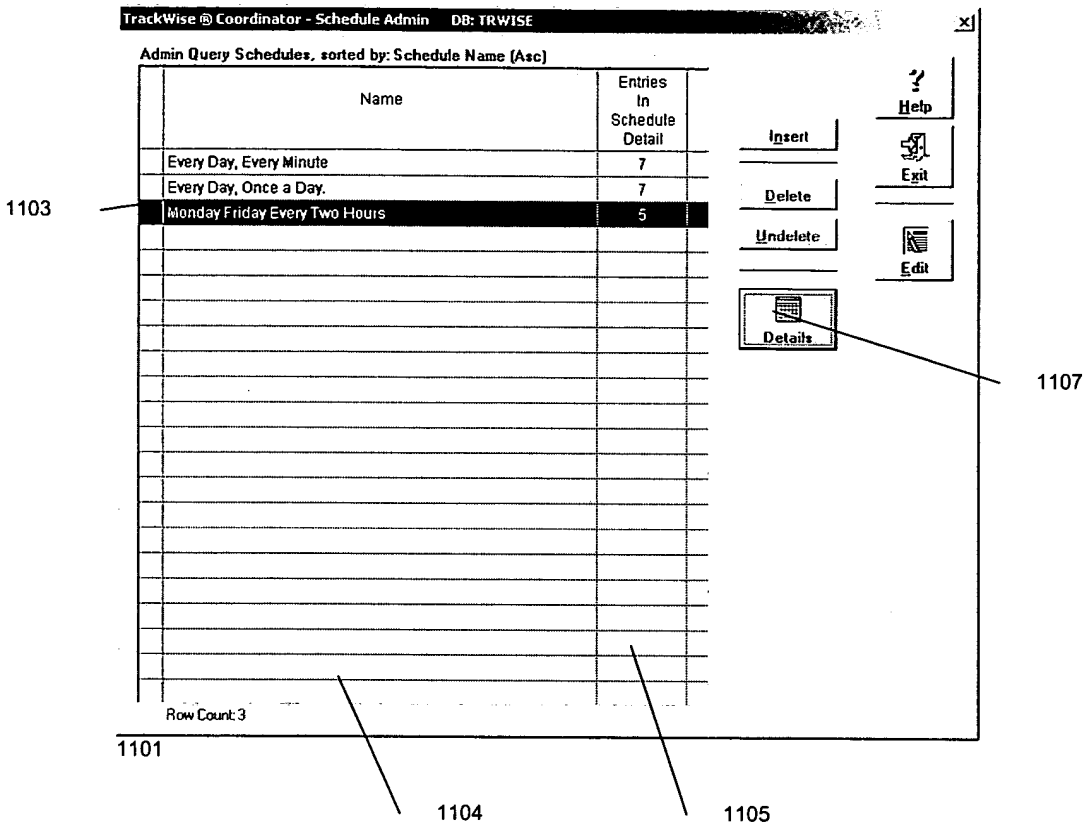

TrackWise ® - Admin Scope Details DB: TRWISE
Admin Scope: Admin Activities
Scope, sorted by: Included in Scope (Desc)
Department
Record Type
Include in Scope
CAPA - New Jersey Action Item
CAPA - California Action Item
CAPA - Ireland Action Item
Audits - Ireland Observation
Audits - California Audit
Audits - New Jersey Observation
Audits - California Observation
CAPA - California Corrective Action
CAPA - California Preventive Action
Audits - New Jersey Audit
CAPA - Ireland Corrective Action
CAPA - Ireland Preventive Action
Audits - Ireland Audit
CAPA - New Jersey Corrective Action
CAPA - New Jersey Preventive Action
Change Control - California Request
Change Control - Ireland Request
Change Control - New Jersey Request
Complaints - California Complaint
Complaints - California Inquiry
Complaints - Ireland Complaint
Complaints - Ireland Inquiry
Help
OK
Cancel
1010
1009
1011
1012
1013

FIG. 10


TrackWise ® Coordinator - Schedule Admin DB: TRWISE
Admin Query Schedules, sorted by: Schedule Name (Asc)
Name
Entries In Schedule Detail
Every Day, Every Minute
7
Every Day, Once a Day.
7
Monday Friday Every Two Hours
5
Row Count: 3
Insert
Delete
Undelete
Details
Help
Exit
Edit
1103
1101
1104
1105
1107

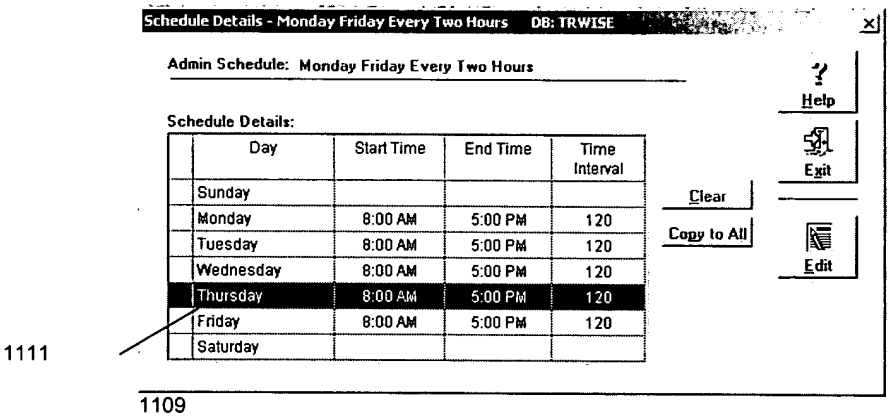

Schedule Details - Monday Friday Every Two Hours DB: TRWISE
Admin Schedule: Monday Friday Every Two Hours
Schedule Details:
Day
Start Time
End Time
Time Interval
Sunday
Monday
8:00 AM
5:00 PM
120
Tuesday
8:00 AM
5:00 PM
120
Wednesday
8:00 AM
5:00 PM
120
Thursday
8:00 AM
5:00 PM
120
Friday
8:00 AM
5:00 PM
120
Saturday
Clear
Copy to All
Help
Exit
Edit
1111
1109

FIG. 11

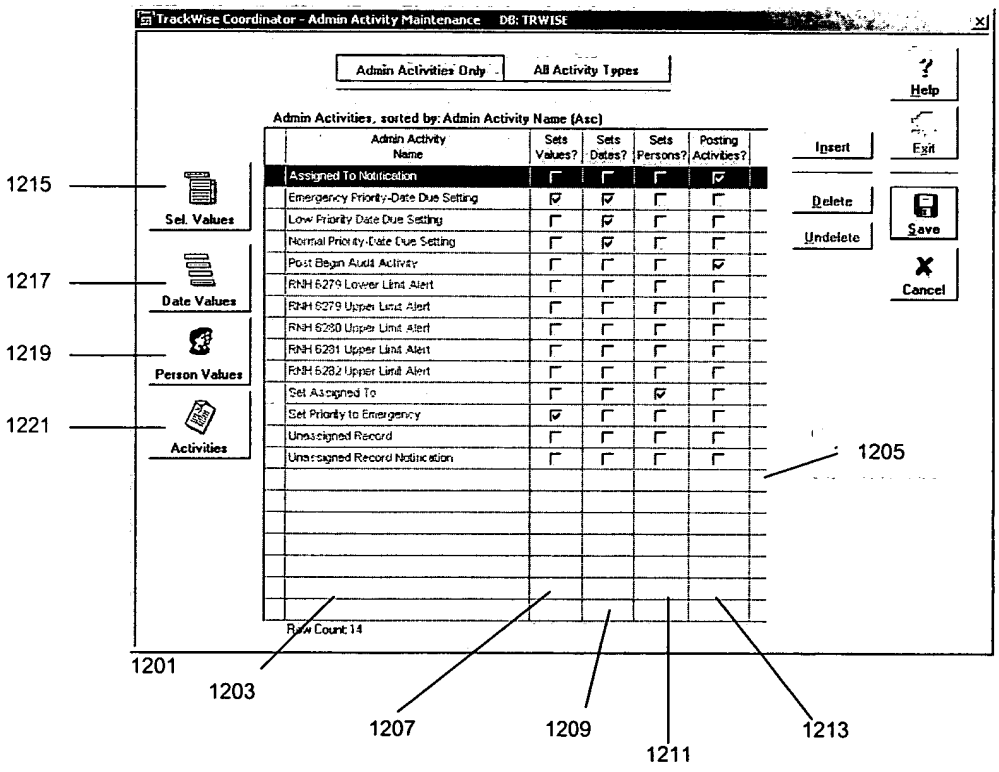
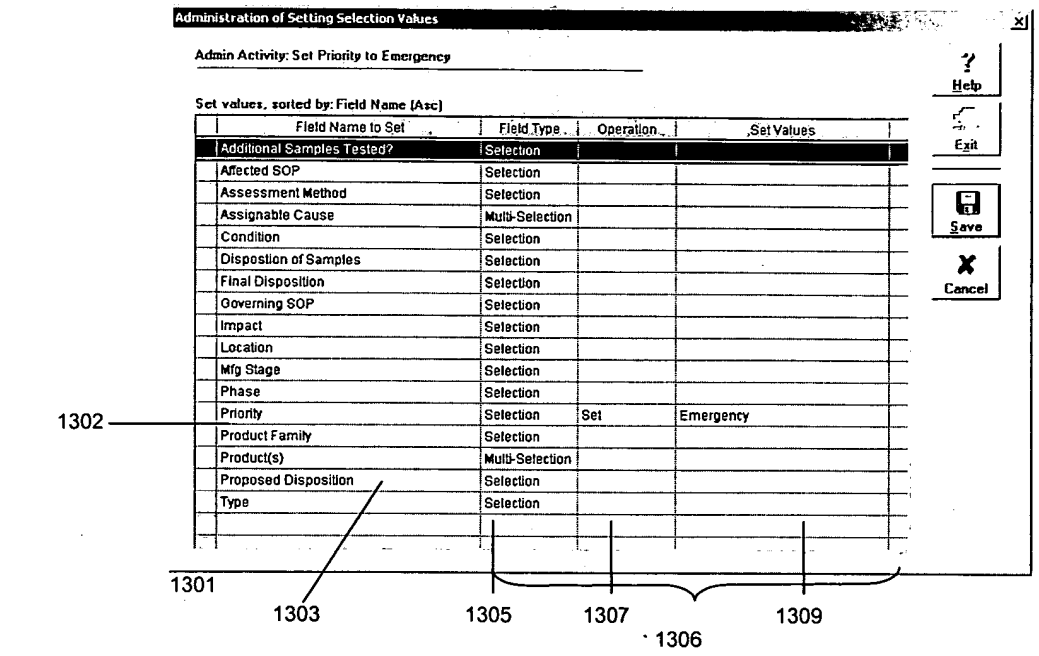
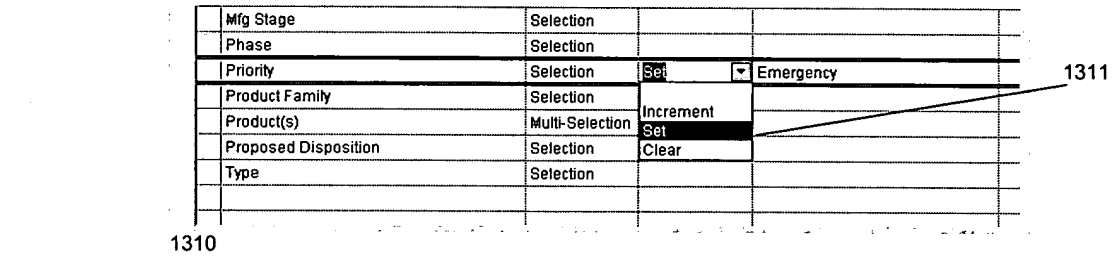

TrackWise Coordinator - Admin Activity Maintenance DB: TRWISE
Admin Activities Only
All Activity Types
Help
Exit
Admin Activities, sorted by: Admin Activity Name (Asc)
Admin Activity Name
Sets Values?
Sets Dates?
Sets Persons?
Posting Activities?
Assigned To Notification
Emergency Priority-Date Due Setting
Low Priority Date Due Setting
Normal Priority-Date Due Setting
Post Begin Audit Activity
RNH 6279 Lower Limit Alert
RNH 6279 Upper Limit Alert
RNH 6280 Upper Limit Alert
RNH 6281 Upper Limit Alert
RNH 6282 Upper Limit Alert
Set Assigned To
Set Priority to Emergency
Unassigned Record
Unassigned Record Notification
Row Count: 14
Insert
Delete
Undelete
Save
Cancel
Sel. Values
Date Values
Person Values
Activities
1201
1203
1205
1207
1209
1211
1213
1215
1217
1219
1221

FIG. 12


Administration of Setting Selection Values
Admin Activity: Set Priority to Emergency
Set values, sorted by: Field Name (Asc)
Field Name to Set
Field Type
Operation
Set Values
Additional Samples Tested?
Selection
Affected SOP
Assessment Method
Assignable Cause
Condition
Disposition of Samples
Final Disposition
Governing SOP
Impact
Location
Mfg Stage
Phase
Priority
Set
Emergency
Product Family
Product(s)
Multi-Selection
Proposed Disposition
Type
Help
Exit
Save
Cancel
1302
1301
1303
1305
1307
1309
1306


Mfg Stage
Selection
Phase
Priority
Set
Emergency
Product Family
Product(s)
Multi-Selection
Proposed Disposition
Type
Increment
Set
Clear
1311
1310

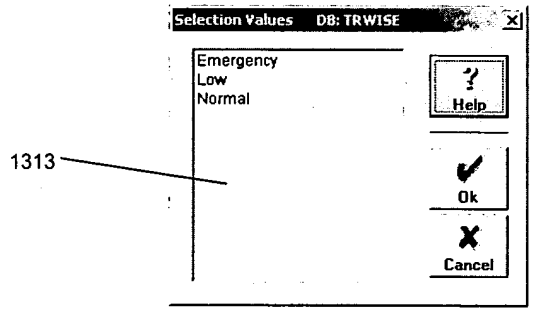
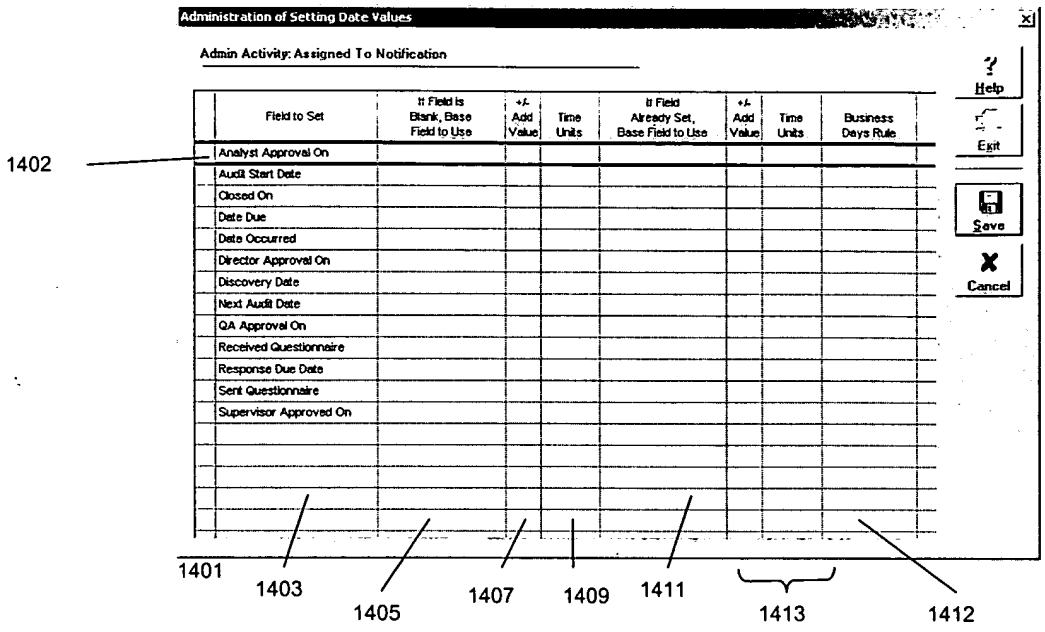
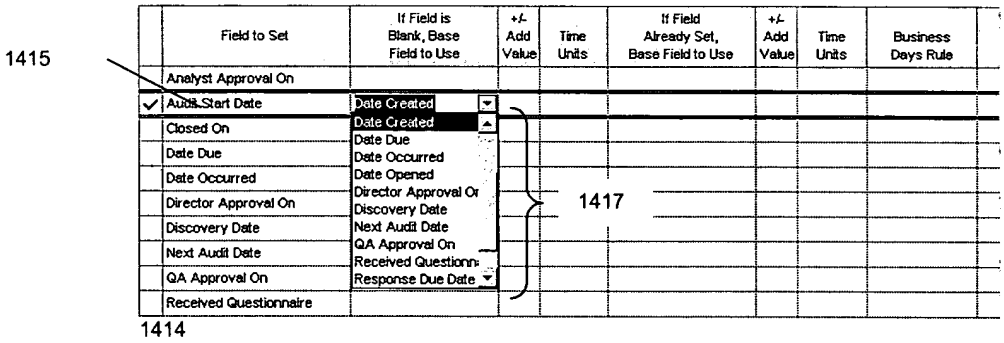
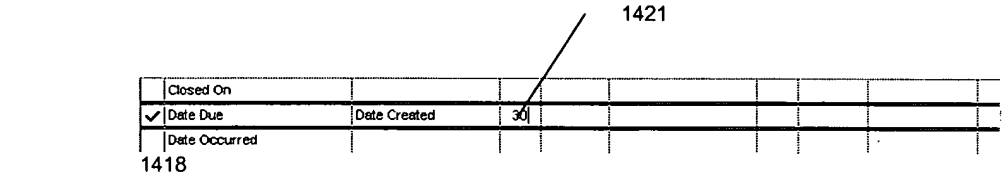

Selection Values DB: TRWISE
Emergency
Low
Normal
Help
Ok
Cancel
1313

FIG 13


Administration of Setting Date Values
Admin Activity: Assigned To Notification
Help
Exit
Save
Cancel
Field to Set
If Field is Blank, Base Field to Use
+/- Add Value
Time Units
If Field Already Set, Base Field to Use
+/- Add Value
Time Units
Business Days Rule
Analyst Approval On
Audit Start Date
Closed On
Date Due
Date Occurred
Director Approval On
Discovery Date
Next Audit Date
QA Approval On
Received Questionnaire
Response Due Date
Sent Questionnaire
Supervisor Approved On
1402
1401
1403
1405
1407
1409
1411
1413
1412


1415
Field to Set
If Field is Blank, Base Field to Use
+/- Add Value
Time Units
If Field Already Set, Base Field to Use
+/- Add Value
Time Units
Business Days Rule
Analyst Approval On
Audit Start Date
Date Created
Date Created
Date Due
Date Occurred
Date Opened
Director Approval Or
Discovery Date
Next Audit Date
QA Approval On
Received Questionn
Response Due Date
Closed On
Date Due
Date Occurred
Director Approval On
Discovery Date
Next Audit Date
QA Approval On
Received Questionnaire
1417
1414


1421
Closed On
Date Due
Date Created
30
Date Occurred
1418

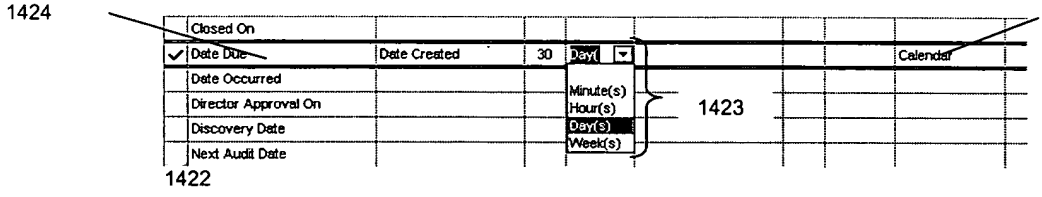
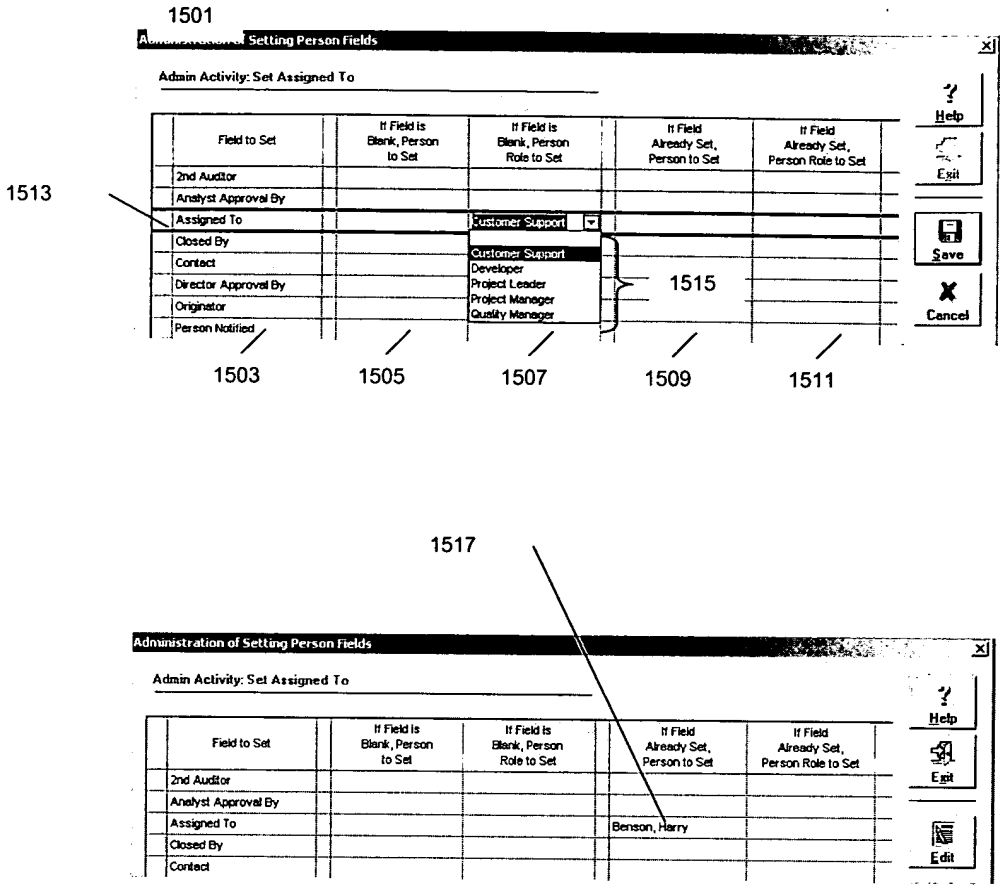
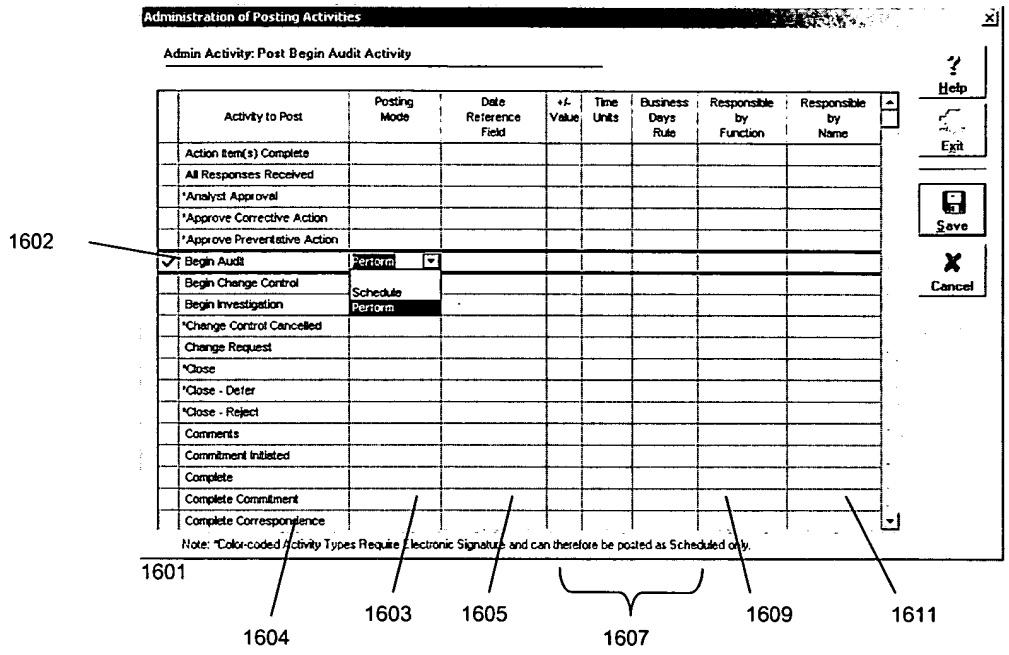

1424
1425
Closed On
Date Due
Date Created
30
Day(
Calendar
Date Occurred
Director Approval On
Discovery Date
Next Audit Date
Minute(s)
Hour(s)
Day(s)
Week(s)
1423
1422

FIG. 14


1501
Setting Person Fields
Admin Activity: Set Assigned To
Field to Set
If Field is Blank, Person to Set
If Field is Blank, Person Role to Set
If Field Already Set, Person to Set
If Field Already Set, Person Role to Set
2nd Auditor
Analyst Approval By
Assigned To
Closed By
Contact
Director Approval By
Originator
Person Notified
Customer Support
Customer Support
Developer
Project Leader
Project Manager
Quality Manager
1513
1515
Help
Exit
Save
Cancel
1503
1505
1507
1509
1511

1517
Administration of Setting Person Fields
Admin Activity: Set Assigned To
Field to Set
If Field is Blank, Person to Set
If Field is Blank, Person Role to Set
If Field Already Set, Person to Set
If Field Already Set, Person Role to Set
2nd Auditor
Analyst Approval By
Assigned To
Closed By
Contact
Benson, Harry
Help
Exit
Edit

FIG. 15


Administration of Posting Activities
Admin Activity: Post Begin Audit Activity
Activity to Post
Posting Mode
Date Reference Field
+/- Value
Time Units
Business Days Rule
Responsible by Function
Responsible by Name
Action Item(s) Complete
All Responses Received
*Analyst Approval
*Approve Corrective Action
*Approve Preventative Action
Begin Audit
Perform
Schedule
Perform
Begin Change Control
Begin Investigation
*Change Control Cancelled
Change Request
*Close
*Close - Defer
*Close - Reject
Comments
Commitment Initiated
Complete
Complete Commitment
Complete Correspondence
Note: *Color-coded Activity Types Require Electronic Signature and can therefore be posted as Scheduled only.
Help
Exit
Save
Cancel
1602
1601
1604
1603
1605
1607
1609
1611

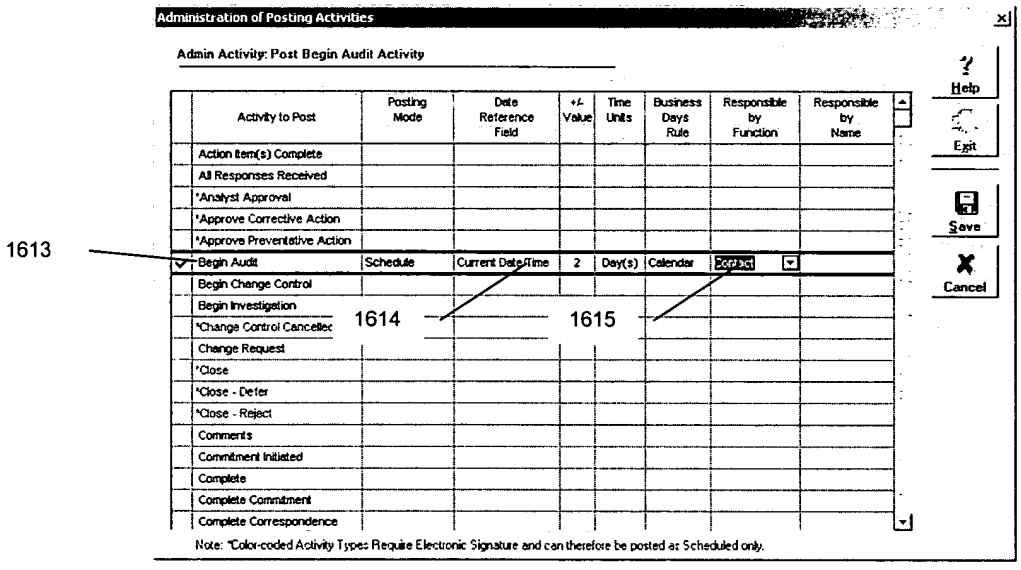
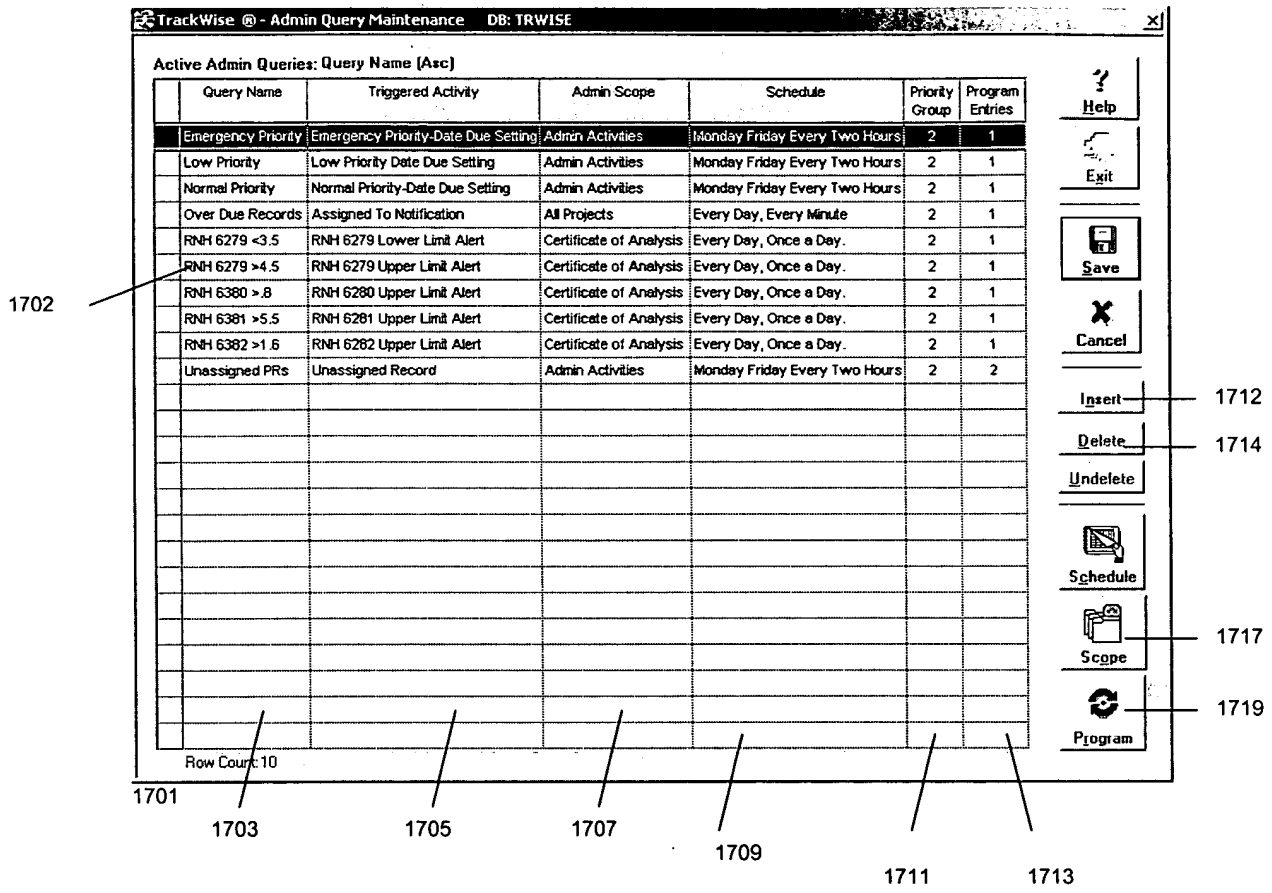

Administration of Posting Activities
Admin Activity: Post Begin Audit Activity
Activity to Post
Posting Mode
Date Reference Field
+/- Value
Time Units
Business Days Rule
Responsible by Function
Responsible by Name
Action Item(s) Complete
All Responses Received
*Analyst Approval
*Approve Corrective Action
*Approve Preventative Action
Begin Audit
Schedule
Current Date/Time
2
Day(s)
Calendar
Begin Change Control
Begin Investigation
*Change Control Cancelled
Change Request
*Close
*Close - Defer
*Close - Reject
Comments
Commitment Initiated
Complete
Complete Commitment
Complete Correspondence
Note: *Color-coded Activity Types Require Electronic Signature and can therefore be posted as Scheduled only.
Help
Exit
Save
Cancel
1613
1614
1615

FIG. 16


TrackWise ® - Admin Query Maintenance DB: TRWISE
Active Admin Queries: Query Name (Asc)
Query Name | Triggered Activity | Admin Scope | Schedule | Priority Group | Program Entries
Emergency Priority | Emergency Priority-Date Due Setting | Admin Activities | Monday Friday Every Two Hours | 2 | 1
Low Priority | Low Priority Date Due Setting | Admin Activities | Monday Friday Every Two Hours | 2 | 1
Normal Priority | Normal Priority-Date Due Setting | Admin Activities | Monday Friday Every Two Hours | 2 | 1
Over Due Records | Assigned To Notification | All Projects | Every Day, Every Minute | 2 | 1
RNH 6279 <3.5 | RNH 6279 Lower Limit Alert | Certificate of Analysis | Every Day, Once a Day. | 2 | 1
RNH 6279 >4.5 | RNH 6279 Upper Limit Alert | Certificate of Analysis | Every Day, Once a Day. | 2 | 1
RNH 6380 >.8 | RNH 6280 Upper Limit Alert | Certificate of Analysis | Every Day, Once a Day. | 2 | 1
RNH 6381 >5.5 | RNH 6281 Upper Limit Alert | Certificate of Analysis | Every Day, Once a Day. | 2 | 1
RNH 6382 >1.6 | RNH 6282 Upper Limit Alert | Certificate of Analysis | Every Day, Once a Day. | 2 | 1
Unassigned PRs | Unassigned Record | Admin Activities | Monday Friday Every Two Hours | 2 | 2
Row Count: 10
Help
Exit
Save
Cancel
Insert
Delete
Undelete
Schedule
Scope
Program
1702
1701
1703
1705
1707
1709
1711
1713
1712
1714
1717
1719

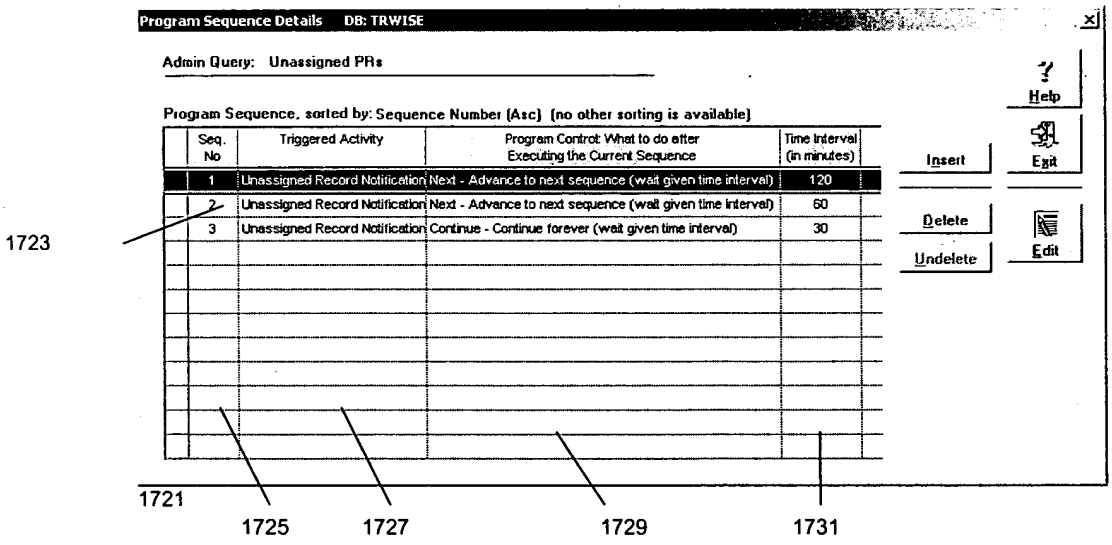

Program Sequence Details DB: TRWISE
Admin Query: Unassigned PRs
Program Sequence, sorted by: Sequence Number (Asc) (no other sorting is available)
Seq. No | Triggered Activity | Program Control: What to do after Executing the Current Sequence | Time Interval (in minutes)
1 | Unassigned Record Notification | Next - Advance to next sequence (wait given time interval) | 120
2 | Unassigned Record Notification | Next - Advance to next sequence (wait given time interval) | 60
3 | Unassigned Record Notification | Continue - Continue forever (wait given time interval) | 30
Help
Insert
Exit
Delete
Undelete
Edit
1723
1721
1725
1727
1729
1731

FIG. 17